



REGULATING MAMMOGRAMS

Citation

REGULATING MAMMOGRAMS (1998 Third Year Paper)

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REGULATING MAMMOGRAMS

Breast cancer is perhaps the most feared disease for women. Although other illnesses might be more deadly from a statistic point of view, women seem more concerned about breast cancer (in fact, breast cancer is the second leading cause of cancer mortality in women). This fear has resulted in an enormous preoccupation with the disease, and in particular, with diagnosing and treating the cancer. And [s]ince currently there is no cure for breast cancer or method to prevent it from occurring, the key to saving women's lives is the early detection of the disease, when treatment is the most effective and survival rates are best.¹ Mammography is widely used as a cancer detection device; unfortunately, it is often misused or performed inadequately. The need for proper supervision and regulation is of a concern to every woman.

I. BREAST CANCER AND MAMMOGRAPHY

In 1997 approximately 180,00 new cases of breast cancer were detected among women in the United States, and around 45,000 women died from the disease.² Breast cancer develops in stages; the ability to detect cancer in those first stages is vitally important to a woman's prognosis

Nih Recommendations on Mammograms: 1-learnings Before the Subcomm. on Labor, Health and Human Services

and Education of the Senate Comm. on Appropriations, in 1997 WL 49424 (1997) (statement of Susan J. Blumenthal, Deputy Asst. Sec. for Health, Asst. Surgeon General, U.S. Public Health Service) [hereinafter *Hearings* 1.

² See American Cancer Society. Breast Cancer information (as of Jan. 23, 1998), available in

<http://www.cancer.org/benIbrstats.html>.

and texture. Mammography is one of the most important detection tools currently available to

women and doctors. In fact, many physicians and experts have agreed that mammography is the best method of detecting breast cancer at its earliest stages.³

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There are two types of mammograms. A screening mammogram (which is the type

discussed in this paper) is an x-ray of the breast used to detect breast cancer in women who have

no signs of cancer. It usually involves two x-rays of each breast. Diagnostic mammograms, by

contrast, are used to diagnose unusual breast changes and used to evaluate abnormalities detected on a screening mammogram. About 23.5 million mammograms were performed in the U.S. in

1994, costing approximately \$2.5 billion.⁵

Mammography is a particularly complex examination. It is one of the hardest

radiological examinations to do properly because the quality of the image is more dependent on

accurate equipment performance and correct processing of film than other types of x-ray exams.,⁶

See Judith Willis, *Why Women Don't Get Mammograms (And Why They Should)*, FDA CONSUMER, May 1987, at

5. Mammography can detect a breast tumor as much as two years before lump can be felt. John Schwartz, *FDA*

Seeks to Improve Quality of Mammography; Rules Set Mandatory Verification System, WASHINGTON POST, Dec. 2,

1993, at A3. At the time of the act's enactment, the National Cancer Institute estimated that annual screening of

women over 50 can reduce breast cancer deaths by about a third. See Leslie Miller, *Mammogram Centers Must*

Meet Standards, USA TODAY, Sept. 30, 1994, at D6 (Life section).

See generally, National Cancer Institute, Cancer Facts: Detection (as of Jan. 23, 1998), available in <http://cancernet.nci.nih.gov/clinpdq/detection/screeningMammograms.html>.

• Rich Weiss, *Mammography Centers Flunking Inspections*, WASHINGTON POST, Nov. 28, 1995, at 5 (Health section).

⁶

HHS Issues Mammogram Guidelines That Seek Better Tests, Faster Results, WASHINGTON POST, Oct. 20, 1994, at A5.

Robert Schmidt, the radiologist in charge of breast imaging at the University of Chicago Hospital,
estimates that probably more than ten percent and as high as thirty percent of a mammogram's

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findings may be wrong - due to human error.

Because mammography is so important, the federal government has felt an obligation to ensure as many women have one as possible. Despite the fact that the exam is vital, many women do not have the exam. The National Cancer institute estimates that only half of the women over 50 (the group at greatest risk of contracting cancer) receive mammograms on a regular basis.⁸

II. DEVICE APPROVAL AND REGULATION

There are two primary areas in which mammography has been heavily regulated by the FDA. One such area is the FDA's regulation of radiological/mammography devices under the medical device program of its Center for Devices and Radiological Health.⁹

Until recently, the regulation of mammography as a medical device received little attention. Because the machines used are the same as the traditional x-ray machines that are used in a wide variety of medical settings, regulation of the actual equipment seemed to be an afterthought. Yet, regular mammography is not full-proof It misses 15-20% of cancers and 80%

Michael Unger, *Digital Mammography Lifts Hopes for Better Detection*, NEWS-DAY, Dec. 19, 1995, at B28. s Sandy Rovner, *Standards Set for Mammograms*, WASHINGTON POST, Nov. 15, 1995, at 18 (Health section).

~ This section primarily deals with diagnostic devices sold to and used by physicians. There is also a new device on the market, which just recently received FDA approval, which helps a woman perform breast self examinations. The Sensor Pad (designed to increase sensation during breast self examinations) can be sold over the counter -originally, in 1995, it was approved by the FDA as a prescription product. See generally, Bruce Ingersoll, *FDA Clears Device for Breast Exams Alter Long Wait*, WALL STREET JOURNAL, Nov. 18, 1997, at B16.

of the lesions found by mammography turn out to be benign. 'ˆ Thus, new technologies and methods are needed to enhance cancer detection. Advances in science and technology have created more complex and novel machines. These new machines must be approved for mammography use by the FDA before they can be marketed as mammography equipment. And the FDA does enforce its rules. In 1997, for example, Biopsys Medical Inc. was forced to stop marketing its product as a cancer detection device after receiving a warning letter from the

FDA.

In fact, these machines are not truly new. Some employ technology that has been utilized in other medical settings. Thus, these devices have already been approved for other uses by the FDA. Yet, equipment that is marketed specifically as a mammography device must first be approved by the agency. However, this does not preclude manufacturers from creating these devices. Furthermore, many physicians use radiological equipment to perform a mammogram that was originally designed for another use. What we regulate is the marketing of the product by the manufacturer. We don't regulate how doctors use the product once it's out on the market said

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an **FDA** spokeswoman. This practice is similar to doctors prescribing drugs that were originally designed for one use to treat another completely different ailment, even though the manufacturer

never marketed the drug for that purpose. Thus, radiological devices do not necessarily need to

¹⁰ *Hearings, supra* note 1.

See Barbara Marsh, *Biopsys Medical Agrees to Alter Promotion of Its Main Product*, Los ANGELES TIMES, Feb. 25, 1997, at D12.

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Dolores Kong, *Better Imaging SecAs to Limit Breast Biopsies*, BOSTON GLOBE, Apr. 22, 1996, at 25.

be approved as mammography devices by the FDA if the manufacturer has no intention of marketing its devices as mammography devices.

However, some manufacturers do want to be able to market their devices to more physicians and hospitals for use as a mammographic machine. As mentioned above, these new devices first need to be approved by the FDA. Approval of such devices has recently received much attention. The new advances are celebrated by physicians and patients alike because they improve the quality of the image taken. This improvement in quality can both save lives (by detecting cancer earlier) and money (by eliminating costly further tests when a mammogram picture is unclear or inconclusive). And of course, manufacturers are asking for approval to be able to market the device to a wider range of customers.

Ultrasound is being used as a possible backup to mammography. In this procedure, the machine builds an image of the breast by sending high frequency sound waves through the body.¹³ The FDA approved the application of Advanced Technology Laboratories (ATL) to market and use ultrasound as a breast cancer diagnostic tool.¹⁴ In its 18 month study of 1,000 women, ATL found that using ultrasound to supplement regular mammograms reduced the number of biopsies

¹³ See John Schwartz, *Feds OK Ultrasound Test of Breast Lumps*, PORTLAND OREGONIAN, Apr. 13, 1996, at A1. ¹⁴ *Id.* ATL was the first company to actually submit clinical data to show the effectiveness and safety of the

procedure, in order to market the device as a breast cancer diagnostic tool. See Kong, *supra* note 12. Although most responses have been positive, ultrasound has its critics. Daniel Kopans, director of the breast imaging division of the Massachusetts General Hospital, simply stated that the approval of the ultrasound machine was a great marketing ploy. Kong, *supra* note 12. Other doctors are more optimistic about magnetic resonance imaging and digital mammography. See *id.*

by a third.¹⁵ ATL's machines give an image sharp enough to allow doctors to distinguish between benign and cancerous solid lumps.¹⁶ The device could also reduce the rate of false positives from 75% to 4100.¹⁷ ATL was forced to seek pre-market approval, rather than conform to a less stringent standard for existing technology.¹⁸

Magnetic resonance imaging creates images from signals generated by the excitation of nuclear particles in a magnetic field.¹⁹ MIRI has emerged as an exciting development because it offers an important advantage: higher definition images without radiation.²⁰ It also is more successful in taking images of younger women, whose breast tissue is usually too thick to produce a readable mammogram. Although the device received FDA approval in 1996, the procedure currently is extremely costly.²¹ Advanced Mammography Systems, Inc. is currently selling this device. However, due to its high cost, the FDA will only allow the company to market the device for diagnosis, not for screening, purposes.²²

¹⁵ See Warren King, *Study: Ultrasound Boosts Accuracy of Mammogram*, NEW ORLEANs TIMES-Picayune, Feb. 4,

1996, at A10. The elimination of unnecessary biopsies is important. In biopsies, a portion of the breast is removed

and analyzed. Although a biopsy is the only 100% certain way to determine the status of an abnormality in the

breast (see Kong, *supra* note 12), many biopsies are performed needlessly. About 70-80% of tissue from these biopsies turns out to be benign. Biopsies are also painful and costly for the patient. See generally, King, *supra*. ¹⁶ Schwartz, *supra* note 13.

~ *Id.*

¹⁸ Kong, *supra* note 12.

¹⁹ *Hearings*, *supra* note 1.

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Eric Convey, *Device to Diagnose Breast Cancer OK 'd*, BOSTON HERALD, Mar. 1, 1996, at 20.

²¹ See generally, *id*

²² See *id.*

Digital mammography is perhaps the most advanced improvement to be developed. Prior to 1995, full breast digital imaging was expensive and inadequate. However, the machines have been refined.²³ The new machines use no film. They take an image of the full breast and display that on a high definition computer screen. That image can then be saved or transmitted elsewhere is necessary. Digital enhancement of the image allows a physician to detect abnormalities that are normally difficult to recognize on a film screen.²⁴ Newer technology has also enabled manufacturers to drop the price of this type of machine. Full breast digital imaging machines were being tested in Northeast areas. A New York company had, as of December 1997, applied for FDA approval to begin marketing the first full-breast digital imaging system.²⁵

Finally, positron-emission tomography that produces molecular images is an experimental method that seeks to distinguish cancer cells from normal tissue based on differences in their metabolism and other characteristics.²⁶

Currently, many of these new mammography machines are being studied or marketed. However, truly accurate and long term studies will ultimately determine the safety and

²³ See generally, Michael Unger, *Digital Mammography Li/Is hopes for Better Detection*, **NEWSDAY**, Dec. 19, 1995, at B28.

²⁴ See *id*

²⁵ See Michael Unger, *led Approval Sought/br Digital Imaging*, **NEWSDAY**, Dec. 3, 1997, at A60. In fact, the

FDA has delineated guidelines for such manufacturers seeking marketing clearance. See Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems (updated Aug. 13, 1996), available in <http://www.fda.gov/cdrh/ode/djgma>. In general, manufacturers must have a system of quality assurance tests in place to ensure that the system is operating properly. See *id*

²⁶ Susan Okie, *More Women are Getting Mammograms*, **WASHINGTON POST**, Jan. 21, 1997, at 7 (Health section).

effectiveness of these methods. In fact, one study will compare various breast imaging devices over a period of five years.²⁷

III. PERFORMANCE REGULATION

The FDA has also regulated mammography by attempting to regulate how well mammograms are performed - by regulating the facilities, doctors, and equipment that are utilized when mammograms are given.

Although recent events and laws have focused attention on the FDA's role in regulating mammograms, the FDA's involvement spans more than just a decade or two. The agency first became interested in mammography in 1974, after a report came out measuring the radiation exposures to women from mammography techniques.²⁸ Thus, the following year the Center for Devices and Radiological Health began the Breast exposure Nationwide Trends program, its objective being to locate facilities giving excessively high radiation exposures and to assist them in reducing the exposures.²⁹ Due to the government's and the manufacturers' involvement, radiation exposure decreased. Attention then focused on the quality of the mammogram's

²⁷ See Helen Bond, *New Technology Makes Breast Cancer Easier to Find*, DALLAS MORNING NEWS, Oct. 27, 1997, at C3.

²⁸ The report was done by Henry Bicehouse, a Pennsylvania state inspector. The report showed that in a few cases,

the level of radiation the woman was exposed to was extremely high. See Marian Segel, *Mammography Facilities Must Meet Quality Standards*, 28 FDA CONSUMER 8 (1994).

²⁹ *Id.*

images. In 1985, the FDA began using a new phantom³⁰ to conduct a nationwide mammographic survey. This study demonstrated the poor quality of some mammograms, due more to human error than to inaccurate mammographic devices.³¹ The problem was handed over to the American College of Radiology (ACR). This prompted ACR to establish its own voluntary accreditation program. At the time, the federal government was also establishing criteria for facilities that wanted to receive Medicare reimbursement. In developing a new system, the government in a sense merged these two programs to create the governing law in place today.

Before the early 1990s, FDA regulation consisted primarily of medical device regulation. Yet there remained a problem - human error. All too often, mammograms do not reflect their full [sic] potential as preventative tools because equipment, physicist, technologist, or radiologist 'error(s)' compromise quality and accuracy.³² Thus, at the urging of Senator Barbara Mikulski and Representative John Dingell, in 1992 Congress passed a law that would allow the FDA to regulate mammography facilities. The regulations created the first such mandatory national program.³³ In general, the act, named the Mammography Quality Standards Act³⁴ (MQSA),

³⁰ A phantom is a plastic device embedded with objects of varying materials and size that is used to evaluate image quality. The device is x-rayed as though it were a breast, and the image score is determined by the number of objects picked up by the x-ray film. *Id.*

³¹ *See id.*

³² Suzanne V. Cocea, *Who's Monitoring the Quality of Mammograms? The Mammography Quality Standards Act of 1992 (Would Finally Provide the Answer)*, 19 AM. J.L. & MED. 313, 315 (1993).

³³

John Schwartz, *FDA Seeks to Improve Quality of Mammography; Rules Set Mandatory Verification System*,

WASHINGTON POST, Dec. 2, 1993, at A3. Mammography quality has also been regulated at the private and state level. *See Cocea, supra* note 32, at 316.

creates quality control standards and a certification system for most of the nation's mammography facilities. The Act's enactment made mammography the only diagnostic imaging test to be

federally regulated for quality.³⁵ The final rules were announced at the end of 1997 to much publicity.³⁶

The implementation of MQSA is delineated into two main areas: accreditation and quality

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standards/certification. The first part of this regulation discusses the procedures whereby an entity can apply to become a FDA-approved accreditation body. The second part established

minimum standards to which a mammography facility must adhere.³⁸

§900.3 of the regulation lays out specific procedures by which an entity can become

accredited. Most importantly, the entity's application submitted to the FDA must discuss the applicant's accreditation review and decision-making process. The following section (§900.4) delineates certain codes of conduct and responsibilities to which the accreditation body must

adhere. The FDA is given the authority to annually evaluate the performance of the accreditation

42 U.S.C. 263(b). It is estimated that the FDA will spend about \$26 million in fiscal year 1997 to implement the act. *See Hearings, supra* note I.

~ Fran Jordan, *Quality Mammograms*, **WASHINGTON POST**, Jan. 17, 1995, (Health section) at 17.

³⁶ *See Clintons Use Radio to Urge Women to Get Mammograms; New Rules are Announced On Breast-Cancer*

Testing, **BALTIMORE SUN**, Oct. 26, 1997, at A3.

~~ Implementation is set forth in 21 C.F.R. § 900 et seq. (1997). ³⁸ *See* 21 C.F.R. §900.1.

body.³⁹ As of 1995, there were four approved accreditation bodies: the ACR, Iowa, California, and Arkansas.⁴⁰

The rules governing quality standards can be divided into three specific areas: personnel, practices, and equipment. All mammography facilities must obtain a certificate issued by the FDA to operate lawfully in the U.S.⁴¹ To receive a certificate, the facility must demonstrate that it is accredited by an approved body, meets the quality standards for equipment, personnel, procedures, and quality control practices, and have a survey by a qualified medical physicist.⁴² §900.12 lists the quality standards applicable to personnel, equipment, medical records, and quality assurance. Interpreting physicians, radiologic technologists, and medical physicists all must have adequate schooling and experience.⁴³ In addition, the equipment used must be specifically designed for mammography.⁴⁴ Facilities also need to prepare written reports of the results of each mammography examination performed.⁴⁵ And finally, mammography facilities will be required to set up quality assurance programs - to ensure that mammograms are clear and to properly follow up cases.⁴⁶ In order to enforce these rules, the FDA (or an authorized inspector)

See 21 C.F.R. §900.5.

⁴⁰ Florence Houn et al., *The Mammography Quality Standard Act of 1992: History and Process*, 50 Food &

DRUG L.J. 485, 488-89 (1995).

⁴¹ See 21 C.F.R. §900.11.

⁴² See Cocea, *supra* note 32, at 331

⁴³ See 21 C.F.R. §900.12(a).

⁴⁴ 21 C.F.R. §900.12(b).

⁴⁵ See 21 C.F.R. §900.12(c).

⁴⁶ See 21 C.F.R. §900.12(d-f).

will annually inspect the facilities. The FDA can suspend or revoke a facility's certificate if it finds that the facility has violated these rules.⁴⁷ Facilities had until October 1994 to comply with the regulations.

The government has taken the MQSA and its rules very seriously. At its inception, a government 1-800 hotline telephone number was set up to provide the names and locations of certified facilities to interested women.⁴⁸ And the FDA has even published a publication to help mammography facilities comply with the requirements of MQSA.⁴⁹

There were high hopes when the standards were first passed. Others feared that small facilities and businesses would be forced to close due to the new rules.⁵⁰ The success of the standards seemed to be apparent in the years after the law was passed. In a very influential report, the General Accounting Office released a study that indicated that the program was a success.⁵¹ According to this report, about four percent of the 10,000 - 11,000 clinics closed rather than comply with the new rules, and in 95% of those situations another clinic was within 25

⁴⁷ 50 C.F.R. §900.14.

⁴⁸ See *Mammogram Hot Line Starts Monday*, **CHICAGO TRIBUNE**, May 14, 1995, 13.

⁴⁹ *Mammography Matters* is a quarterly publication of the Division of Mammography Quality and Radiation Programs, Center for Devices and Radiological Health.

⁵⁰ For some additional detailed information, refer to Economic Impact Analysis of Regulations Under the Mammography Quality Standards Act of 1992 (Oct. 7, 1997), available in

<http://www.fda.gov/cdihieci/mana.html>.

⁵¹ Senator Nancy Kassebaum had requested the report in response to concerns that the FDA rules would put many

clinics out of business and would cost too much. *tinder Examination*, 12 **MED. MALPRACTICE L. & STRATEGY** 8 (1995). The GAO report was released in November of 1995,

miles.⁵² Furthermore, although 3500 of the facilities that were investigated failed to comply with one of the rules, most of them passed on subsequent inspections.⁵³

After this report was released, everyone viewed the law as a success: We have delivered to American women better quality mammograms and we have ensured that no matter whether a woman lives in a big city or a small town, she has access to this lifesaving service, Donna Shalala, the Secretary of Health and Human Services, stated.⁵⁴ There have been some people who have felt otherwise – the report also states that one-third of the facilities originally certified failed the subsequent investigation.⁵⁵ As of June 1995, 1,843 facilities had been inspected. 601 facilities had violations, and 119 of these were serious violations - usually involving unqualified personnel.⁵⁶ In the latest GAO report, the agency found that although some problem areas do exist, overall there is growing compliance with the mammography standards.⁵⁷

⁵² See *Under Examination*, 13 **MED. MALPRACTICE L. & STRATEGY** 8 (1995).

⁵³ See *id*

⁵⁴ *US Reports a Healthier Mammogram Picture*, **WASHINGTON POST**, Nov. 2, 1995, at A3. The report was also used for larger, political reasons. Representative Dingell seized the report as evidence that Congress should be cautious in heeding calls by FDA critics to revamp - or even privatize - the agency. *US Reports a Healthier Mammogram Picture*, **WASHINGTON POST**, Nov. 2, 1995, at A3.

⁵⁵ See Rich Weiss, *Mammography Centers Flunking Inspections*, **WASHINGTON POST**, Nov. 28, 1995, at 5 (Health section).

⁵⁶ See *id*

⁵⁷ See U.S. General Accounting Office, Report to Congressional Committees, FDA's Mammography Inspections:

While Some Problems Need Attention, Facility Compliance Is Growing, GAO/HEHS-97-25 (Jan. 1997). GAO found the following problems: more consistent reporting is needed, the procedures for assessing image quality need strengthening, and the enforcement process does not ensure timely correction of deficiencies. See *id*.

IV. PROBLEMATIC ISSUES

Although regulation of mammography has largely proved to be beneficial, some problems still remain. In enforcing the MQSA, the FDA faced a (all too familiar) problem of implementation. With limited resources and labor, the FDA was required to inspect and certify thousands of facilities. At the time, FDA Commissioner David Kessler was optimistic: It is an all-out effort. I have no doubt the goal is achievable.⁵⁸ To help achieve its goal, the FDA invited the help of other entities. The FDA has relied on its decades-long alliance with state departments.⁵⁹ The FDA does do some of its own investigations, however it primarily trains and provides technical expertise to state inspectors. In addition, the standards adopted under the MQSA were very similar to the voluntary accreditation standards of the American College of Radiology in the 1980s. Because nearly 60% of the facilities adhered to those standards, the FDA's undertaking seemed less daunting.

A further interesting problem is how the issue of scientific certainty is dealt with in the regulation of mammography. To date, the FDA has not issued any guidelines recommending who should take annual mammograms or when women should start getting mammograms. The FDA has (wisely?) stayed out of this debate. The problem is simple: when should women start having mammograms? The solution is far from clear. The National Cancer Institute (NCI) and the American Cancer Society have been debating the issue for some time. Initially, the NCI recommended that women start having mammograms every year or two at age 40. However, around 1993 it changed its position, stating that women under 50 should look at all the facts and

~ Schwartz, *supra* note 13.

~ John Henkel, *FDA, States Collaborate For Sa~ty's Sake*, 30 FDA CONSUMER 27 (1996).

decide for themselves. This new position conflicts with the views held both by the American Cancer Society and the American Medical Association.⁶⁰

This problem is indicative of the inevitable uncertainty of science. Thus far there is no way to prove definitely that women under 50 should or should not have annual mammograms. Recommendations are, at best, made out of educated guesses. Further complicating matters, there is some debate regarding the safety of mammograms and their effectiveness in detecting cancer in young women.⁶¹ And in a telling policy choice, the FDA has decided to not address the (real) issue.

A final point to mention is the amazing coverage and attention mammography has received recently. As we all know, the FDA has a limited budget. Devoting resources to one problem siphons funds away from other worthy causes. Yet, the FDA has decided that mammography in particular, and breasts in general, should be a priority item. Even the Clinton administration addressed the issue as part of its focus on women and health. The broad regulation of mammography, together with the immense attention given to breast implants, suggests that the FDA just might be breast obsessed. Has pressure from the public and from women's groups forced the FDA to make choices it normally would have shied away from? Or is the FDA simply responding to a killer disease that has struck down many women and that can be preventable/treatable if caught early enough?

⁶⁰ See John C. Goodman, *Choice Not Offered* *for Mammograms*, **WALL STREET JOURNAL**, Feb. 3, 1997, at A14;

American Cancer Society, Workshop on Guidelines for Breast Cancer Detection, Mar. 7-9, 1997, *available in*

<http://www.cancer.org/mammog.html>.

⁶¹ The link between mammograms and the potential adverse effects of radiation exposure is still being studied and debated.